

REMARKS

Claims 42 and 49 have been cancelled. The claims now present in this application are claims 37-41, 43-48 and 55-58.

Claim 56 has been amended so that the benzodiazepine has been limited to 1,4-benzodiazepines which are substituted in both the 7 and 8 positions of the benzodiazepine ring. In fact, all of the claims in this application have been limited to the 7, 8 di-substituted 1,4 benzodiazepines of the elected invention. Therefore, claim 56 no longer reads upon the species disclosed in the Plunkett et al. article. In view of this claim 56 as well as claims 37, 38, 43 and 44 are not anticipated. Nothing in the Plunkett et al. reference renders obvious the claimed compounds as set forth in newly amended claim 56. This is true because the Plunkett article only discloses 7-methoxy substituted benzodiazepines. There is no disclosure in the Plunkett article of any benzodiazepine having it's A ring di-substituted, much less a 7,8-benzodiazepine such as presented in the claims in this application. Therefore, claim 56 as well as all of the remaining claims in this application are not obvious, much less anticipated by the Plunkett et al. article.

In addition claim 56 has been amended so that the phrase "and pharmaceutically acceptable salts thereof" has been changed to appropriate alternative language recommended in the Outstanding Office Action. It is submitted that the rejection under 35 U.S.C. § 112 second paragraph is obviated.

In view of the allowability of the linking claims, particularly claims 56, as well as 37-41 and 43- 48, it is submitted that all of the claims are allowable in accordance with the allowance of the elected species. In view of the allowance of the linking claim,

particularly claim 56, all of the claims should be examinable and allowable in this application.

That an application contains a claim which covers two or more possibly divisible inventive species does not make a requirement for restriction or election proper when there is present a properly allowable linking claim generically covering, via a Markush Group, these individual species. These linking claims make these species inseparable from each other especially when they are embraced within a Markush Group. It is this linking claim which links these invention, otherwise divisible. This is in accord with Art. (3)4 III and Rule 13.1 of the Patent Cooperation Treaty, as well as U.S. Patent Law. None of these require that the common feature which links all of the species be inventive.

Under the rules of the Patent Cooperation Treaty and the U.S. Patent Laws, when an allowable linking claim is present in an application, there is unity of invention. In this case, under the Patent Cooperation Treaty and the MPEP, no division requirement is proper. Under Rule 13.4 of the PCT Regulations, unity of invention also applies to dependent claims

“claiming specific forms of the invention  
claimed in an independent claim, even where the  
features of any dependent claim could be considered  
as constituting in themselves an invention.”

As seen from Rule 13.4, the provision of linking claims which cover all compounds, satisfies the requirement of unity of invention. By such claims, a plurality of separate inventions covered under the Markush group are linked as to form a single, general inventive concept which is present in an allowable generic claim. It can be seen that all of these claims include a common structure whose separate inventions are

designated through members of a Markush group. In addition, all of the compounds included within the generic claim 56 are defined by a common structure, as well as a common property and activity, i.e., they are active as inhibitors of cyclic nucleotide phosphodiesterase, therefore, the generic linking claims satisfy Annex B, part 1(f) of PCT Rule 13.2. There is no rejection against these linking claims.

Also, please note MPEP §809.03 which requires that:

“Examiners should use Form Paragraph 8.12 to make restrictions involving linking claims.”

“Claim [1] link(s) inventions [2] and [3]. The restriction requirement [4] the linked inventions is **subject to** the nonallowance of linking claim(s), claim [5]. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.”

Please note that, under MPEP 809.04, like the PCT, once the linking claim is allowed, the restriction requirement should be canceled. Therefore, Applicant is allowed to present linking claims in conjunction with claims directed to these species.

With respect to all members of a Markush Group, all that the PCT Rules require is that all the species embraced within a single allowable generic claim have a common structural feature or activity in order to provide proper unity of invention. These rules governing unity of invention are not concerned with whether the species within the generic Markush Group may be classified in various groups within the U.S. classification system or that they require separate searches of the chemical literature. This is not a requirement of the unity of invention under the PCT Treaty or Rules since the various

separate inventive species of this application are members of a generic Markush Group where these species have a common structural feature and activity, .

It is well-established law that restriction within a single claim cannot be sustained under 35 U.S.C. §121. As is stated in *In re Weber*, 198 U.S.P.Q. 328 (CCPA 1978) at pages 331-332,

“§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be “independent and distinct.” It is not, however, provide a basis for the Examiner acting under the authority of the Commissioner to *reject* a particular *claim* on that same basis.” (Emphasis in original text).

The instant Office Action makes the exact type of restriction expressly forbidden by the CCPA in *In re Weber* (such restriction is tantamount to a rejection). There is no basis under 35 U.S.C. §121 for the Patent Office to make an intraclaim restriction requirement of claim 1 and the subsequent generic claims encompassing the species of claim 137.

Nothing in 35 U.S.C. §121 gives the legal authority to create a “generic concept” and require applicants to amend a particular claim so as to only claim the subject matter limited to embrace the “generic concept.” Applicants have the right under U.S. patent law to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the requirements of 35 U.S.C. §112 are met. See *In re Weber* at 331.

When a new “generic concept” is created numerous issues arise as to who is the inventor of the “generic concept” and whether the specification provide the requisite written description required by 35 U.S.C. §112, first paragraph, of the “generic concept”? Although every species contained within the “generic concept” would be enabled by the specification, the new “generic concept” *per se* could lack a written description required by 35 U.S.C. §112, first paragraph, in the specification as filed. This is the exact situation envisioned in *In re Weber* which states on page 331:

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner, rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

Based upon the foregoing, it is submitted that the Restriction Requirement be withdrawn since there is no rejection of the linking claims. Therefore, all claims are allowable.

### **Correspondence and Fees**

Please charge the Petition for One Month Extension of Time fee of \$130.00 to Deposit Account No. 03-3839. Authorization is hereby given to charge Deposit Account No. 03-3839 for any underpayment, or to credit any overpayments.

Please address all correspondence to Intellectual Property Docket Administrator, Gibbons, P.C., One Gateway Center, Newark, New Jersey 07102-5310. Telephone calls should be made to William H. Epstein at (973) 596-4607 and fax communications should be send directly to him at (973) 639-6397.

Respectfully submitted,



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